EUROPEAN CHEMICALS AGENCY

Helsinki, 9 July 2018

Addressee: [redacted]

Decision number: CCH-D-2114432930-54-01/F
Substance name: (E)-anethole
EC number: 224-052-0
CAS number: 4180-23-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 11/03/2016
Registered tonnage band: 100-1000

## DECISION ON A COMPLIANCE CHECK

Based on Article 41(1)(a), (c) and (3) of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Identification of DNEL(s) and risk characterisation (Annex I, Section 1.4. and 6.): revise DNEL(s) for long-term systemic effects via inhalation and dermal routes for workers and for the general population using the assessment factors recommended by ECHA and revise the risk characterisation accordingly *or* provide a detailed justification for not using the recommendations of ECHA Guidance R.8 for DNEL derivation;**

2. **Identification of PNEC and risk characterisation (Annex I, Section 3.3.1. and 6.): derive PNECs for marine water, freshwater sediment, marine sediment and soil**
   - **using the study giving rise to the highest concern according to Annex I, Section 3.1.5 and revise the risk characterisation accordingly or provide a detailed justification for not using the study giving rise to the highest concern;**
   - **using the assessment factors according to ECHA Guidance R.10 for PNEC derivation and revise the risk characterisation accordingly or provide a detailed justification on how the chosen approach meets the general requirements for identification of the PNEC as described in Section 3.3. of Annex I if not using the recommendations of ECHA Guidance R.10 for PNEC derivation.**

3. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health:**
   - **revise worker contributing scenarios for uses which have RCRs above 1,**
   - **revise worker contributing scenarios demonstrating the hierarchy of risk management measures or justify if collective measures are not feasible**
   - **revise exposure assessment demonstrating safe use using a model within its applicability domain *or* provide adequate measured**

**representative exposure data and**
- **revise the risk characterisation accordingly;**

4. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: revise worker exposure assessment demonstrating the likelihood that skin sensitising effects are avoided for all identified uses, and to document in appropriate detail the operational conditions and risk management measures and revise the risk characterisation accordingly;**

5. **Exposure assessment and risk characterisation (Annex I, Section 5.1.1.) for human health: provide documentation for the recommended personal protective equipment, *i.e.* skin protection (hand and body protection) and respiratory protection;**
   - **specify the type of glove material, and breakthrough times;**
   - **specify the filter type/class for the respiratory protective equipment;**
   - **specify the type and quality of protective clothing.**

6. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health: revise consumer exposure assessment demonstrating the likelihood that skin sensitising effects are avoided for consumers (ES7, ES8 and ES9) and detail the operational conditions and risk management measures and revise the risk characterisation accordingly;**

7. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment: use default release factors and revise the environmental exposure assessment and the risk characterisation accordingly or provide a detailed justification for not using the default release factors;**

8. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment:**
   - **report the conditions of uses applicable to exposure scenarios 8 and 9,**
   - **ensure the consistency in the information provided on the exposure scenarios through the different sections of your CSR, and**
   - **revise your exposure assessment and risk characterisation accordingly.**

You have to submit the requested information in an updated registration dossier by **16 January 2019**. You also have to update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirements of Annex I and VI to the REACH Regulation.

## Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by **Ofelia Bercaru**, Head of Unit, Evaluation **E3**

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

**Appendix 1: Reasons**

CHEMICAL SAFETY ASSESSMENT

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

## 1. Identification of DNEL(s) and risk characterisation (Annex I, Sections 1.4. and 6.)

According to Article 14(4) and Annex I, Section 1.0, of the REACH Regulation, one of the objectives of human health hazard assessment is to derive levels of exposure to the substance above which human should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).

Annex I, Section 1.4.1 of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

If it is not possible to identify a DNEL, this must be clearly stated and fully justified (Annex I, Section 1.4.2)

The ECHA Guidance on information requirements and chemical safety assessment Chapter R.8 provides further details and specifically provides default factors, which should be applied to derive DNELs in the absence of substance specific information to fulfill the REACH obligations.

ECHA notes that the assessment factors (AF) applied were not derived in accordance to the default assessment factors recommended in the ECHA Guidance R.8 for DNEL derivation.

ECHA observes that you have not followed recommendations of ECHA's Guidance R.8 for DNEL derivation and you have not provided a full justification for such DNELs derivation in line with Annex I, 1.4.1. In particular, ECHA notes that for the systemic long term DNELs for inhalation route and dermal route both for workers and for the general population you have not applied the additional default assessment factor of 2.5 to address the remaining interspecies differences. If no substance specific data are available, the additional factor of 2.5 for other interspecies differences is to cover the uncertainty of toxicokinetic differences not related to metabolic rate and toxicodynamic differences.

As explained above, the information provided on DNEL for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 1.4.1.

Consequently, you are given two options: you shall revise the DNELs for workers and for the general population by applying the assessment factors recommended by ECHA that are appropriate in this case as specified above. Subsequently, you shall re-assess related risks.

In the alternative, you shall, in accordance with Annex I, Section 1.4.1, provide a full justification for the DNELs derived for workers and for the general population provided in the chemical safety report by specifying how the following has been taken into account:

1. the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
2. the nature and severity of the effect;
3. the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies; and that
4. DNELs reflect the likely route(s), duration and frequency of exposure.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise DNEL(s) for long-term systemic effects via inhalation and dermal routes for workers and for the general population using the default assessment factors and other recommendations of ECHA Guidance R.8 for DNEL derivation and revise the risk characterisation accordingly *or* provide a detailed justification for not using the recommendations of ECHA Guidance R.8 for DNEL derivation.

## 2. Identification of PNEC and risk characterisation (Annex I, Sections 3.3.1. and 6.)

According to Article 14(4) and Annex I, Section 3.0.1, of the REACH Regulation, one of the objectives of environmental hazard assessment is to identify the concentration of the substance below which adverse effect in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No-Effect Concentration (PNEC).

Annex I, Section 3.3.1. of the REACH Regulation requires to establish a PNEC for each environmental sphere based on the available information and to use an appropriate assessment factor to the effect values.

The ECHA *Guidance on information requirements and chemical safety assessment,* Chapter R.10 (May 2008), provides further details and specifically provides default assessment factors which should be applied to derive PNECs.

Further, according to Annex I, Section 3.3.2., if it is not possible to derive the PNEC, then this shall be clearly stated and fully justified.

You have not established the PNECs for the following environmental compartments: marine water, freshwater sediment, marine sediment and soil using the following justification: "*no data available*".

ECHA notes that you have provided enough data to be able to calculate the missing PNECs and you have not provided an acceptable justification for not having done so. According to the information provided in the technical dossier, exposure of these compartments cannot be excluded.

Consequently, it is necessary to derive the PNECs.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to derive PNECs for marine water, freshwater sediment, marine sediment and soil:

- using the study giving rise to the highest concern according to Annex I, Section 3.1.5 and revise the risk characterisation accordingly *or* provide a detailed justification for not using the study giving rise to the highest concern;
- using the default assessment factors and other recommendations of ECHA Guidance R.10 and revise the risk characterisation accordingly *or* provide a detailed justification on how the chosen approach meets the general requirements for identification of the PNEC as described in Section 3.3. of Annex I if not using the recommendations of ECHA Guidance R.10 for PNEC derivation.

EXPOSURE ASSESSMENT AND RISK CHARACTERISATION FOR HUMAN HEALTH

According to Article 14(4), the chemical safety report must include an exposure assessment and risk characterisation in the chemical safety assessment if the substance fulfils the criteria for any of the hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 or is assessed to be a PBT or vPvB.

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

The exposure assessment shall entail the following two steps, which shall be clearly identified as such in the Chemical Safety Report (CSR):

Step 1. The generation of exposure scenario(s) or the generation of relevant use and exposure categories.
Step 2. Exposure estimation.

The generation of exposure scenarios should include, where relevant, a description of operational conditions such as the activities of consumers and the duration and frequency of their exposure to the substance, and risk management measures to reduce or avoid direct and indirect exposure of humans including workers and consumers. An estimation of the exposure levels shall be performed for all human populations including consumers.

Annex I, Section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and to consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in Section 5 of the same Annex have been implemented.

## 3. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health; worker's quantitative exposure assessment

You have provided exposure scenarios (ES) with exposure estimates and risk characterisation ratios (RCRs) in the CSR. The model used by you to predict quantitative exposure levels is ECETOC TRA version 3.

ECHA notes that the quantitative worker exposure assessment contains the following deficiencies:

1. Your ESs show high exposure potential through dermal contact and via inhalation and you have provided many ESs where the combined RCRs are above 1. For example, the RCR is [redacted] (use 1 and 2) in worker contributing scenario (WCS)13 in ES4 (Industrial end-use of washing and cleaning products) and [redacted] (use 2) in WCS3 in ES5 (Professional end-use of washing and cleaning products). ECHA notes that the ESs should describe safe conditions of use and to demonstrate this, the RCRs should be below 1.

2. You have not followed the hierarchy of risk management measures (RMM) for reducing exposure in all your exposure scenarios. In your ES1 worker contributing scenarios 5, 6 and 7, you have not recommended the use of collective protective measures such as local exhaust ventilation (LEV) as a priority risk management measure. Instead of that you have indicated only the use of personal protective equipment as an individual risk management measure. Also in some worker contributing scenarios in ES2 and ES3, you have provided two sets of conditions of use. In one of the two sets of conditions of use, you have not followed the hierarchy of RMM. ECHA notes that ECHA's Guidance (Version 1.2, October 2012) Chapter R.13, page 9, outlines that the hierarchy of RMM prescribed in the Chemical Agents Directive 98/24/EC must be followed and this includes in particular combating the risks at source and giving collective protective measures priority over individual protective measures. If collective protective measures are not feasible, you should provide a justification for not following the hierarchy of RMM.

3. For spraying (PROC 7 and PROC 11) and for rolling and brushing activities (PROC 10), inhalation exposure is mostly due to aerosol generation and the ECETOC TRA model does not predict this. In this context, the inhalation exposure of the registered substance, which has a low vapour pressure (vp 5.45 Pa at 20°C), may be underestimated and the estimated worker exposures may be associated with a higher level of uncertainty. ECHA notes that for example, the combined RCRs are [redacted] and [redacted] in the WCS7 (PROC 10) and WCS8 (PROC 11), respectively, in ES5 (Professional end-use of washing and cleaning products). If the aerosol formation had been taken into account in the exposure estimation, the use might be concluded as being even more unsafe (an RCR>>1).

4. You have used the local exhaust ventilation (LEV) modifier within the ECETOC TRA model when predicting dermal exposure e.g. WCS2 (use 2) and WCS4 in ES6 (Professional use of polishes and wax blends). ECHA notes that *ECHA Guidance on information requirements and chemical safety assessmen*t (Version 3.0, August 2016) Chapter R.14, Appendix R.14-1.1, page 52, outlines that for low volatility substances surface contamination levels are largely not affected by the rate of evaporation. Therefore, the dermal exposure is underestimated compared to measured data in situations with LEV and to compensate for this limitation, the LEV should be set to "0" to reach a conservative estimate. ECHA notes that the registered substance is a liquid with a low vapour pressure and application of LEV will have little effect on potential dermal exposure at the workplace.

ECHA notes, that the quantitative (or the semi-quantitative) assessment should be carried out according to ECHA's *Guidance on information requirements and chemical safety assessment* Part E, Risk characterisation (version 3.0, May 2016), section E.3, Chapter R.13 Risk management measures and operational conditions for occupational risk management (version 1.2, October 2012) and Chapter R.14 Occupational exposure assessment (version

3.0, August 2016). Further, Annex I, Section 5.2.5. states that appropriate models can be used for the estimation of exposure levels. However, special consideration shall be given to representative exposure data where available, when conducting the exposure assessment. Following REACH Regulation Annex I, Section 6.4 and ECHA's Guidance Part E and Chapter R.14, the risk to humans can be considered to be adequately controlled, if the exposure level estimates do not exceed the appropriate DNEL (derived no effect level) and RCR (risk characterisation ratio) are below 1. In addition, according to ECHA's Guidance Chapter R.13 for achieving safe use in the ESs, the hierarchy of RMM prescribed in the Chemical Agents Directive 98/24/EC must be followed.

ECHA notes, that you are using exposure estimates in your exposure scenarios, which have been calculated by using a model in an inappropriate manner, and the RCRs are above 1 in many ESs. For predicting exposure levels from aerosol applications and assessing the associated risks, ECHA recommends using more appropriate exposure models such as ART or Stoffenmanager and, where available, measured data. However, in case of sensitizing substances like this one, for dermal exposure and control of risk to the necessary level, the qualitative approach to propose suitable and adequate measures to prevent exposure is preferred. For spraying tasks, there is a need to consider adequate control of exposure to aerosol for both the inhalation and dermal routes. You should provide sufficiently detailed descriptions of RMMs, which should be implemented for controlling inhalation and dermal exposure in all relevant contributing scenarios. ECHA also notes that the quantitative exposure estimations should be consistent with the qualitative risk characterisation in the CSR.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise the following:

- worker contributing scenarios for uses which have RCRs above 1,
- worker contributing scenarios demonstrating the hierarchy of risk management measures or justify if collective measures are not feasible,
- exposure assessment demonstrating safe use using a model within its applicability domain and in accordance with the guidance for the model used *or* provide adequate measured representative exposure data, and
- the risk characterisation accordingly.

## 4. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health; worker's qualitative exposure assessment

You have provided exposure scenarios (ES) with exposure estimates and risk characterisation ratios (RCR) in the CSR. The model used by you to predict quantitative exposure levels is ECETOC TRA version 3. You have classified the registered substance as a skin sensitiser class 1. In the CSR, you claim that the local effects are "*covered by systemic effects long-term exposure*".

ECHA notes that the worker exposure assessment contains the following deficiencies when dealing with the sensitising properties of the registered substance:

1. Your statement that the local effects (sensitising effect) are covered by the DNEL for systemic effects is not valid. The DNEL for systemic effects does not cover the local effects, especially for substances with sensitising properties. You claim that the DNEL for the sensitising effect cannot be derived. ECHA notes that in such cases a qualitative or a semi-quantitative exposure risk assessment should be performed in

order to make sure that the contact with the substance is prevented by technical measures.

2. You have classified the registered substance as a skin sensitiser (Skin Sens. 1), which belongs to the high hazard band, but you have not provided a qualitative exposure and risk assessment in your ESs. Your ESs show high exposure potential through dermal contact and also via inhalation. For example, the dermal exposure has been estimated to be [redacted] in WCS9 (PROC 19 – manual activities involving hand contact) in ES3 (Formulation of fragranced end-products). No need for gloves were identified in the operational conditions (OC). The potential for inhalation exposure in some professional uses is also predicted to be high (e.g. [redacted] and [redacted] in PROC 8a in WCS5 and PROC 9 in WCS6 in ES5 (Professional end-use of washing and cleaning products), respectively). These kind of OCs and ESs cannot be considered as safe use conditions for a sensitising substance. ECHA notes that you should consider the OCs and RMMs, which are applicable to a substance that belongs to the high hazard band, and the qualitative assessment should describe how to *prevent* the contact with the substance through dermal contact and inhalation.

3. Your exposure and risk assessment is lacking elements like training for staff on good practice, management/supervision in place and the description of suitable and adequate PPE for workers' protection. (See request 5 below addressing "Specification of PPE").

ECHA notes, that for substances that have both local and systemic effects, the semi-quantitative exposure assessment should be carried out according to ECHA's *Guidance on information requirements and chemical safety assessment,* Chapter E, Risk characterisation (version 3.0, May 2016), section E.3. Further advice is provided in Practical Guide 15 (November 2012), How to undertake a qualitative human health assessment and document it in a chemical safety report.

ECHA notes, that the above mentioned essential parts of the qualitative assessment are missing from the CSR. The exposure scenarios should include a sufficiently detailed description of the OCs and RMMs that are to be applied to prevent dermal contact and exposure via inhalation for the manufacture stage and identified uses of the substance through the supply chain. The quantitative exposure estimations should be consistent with the qualitative risk characterisation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise worker exposure assessment demonstrating the likelihood that effects for skin sensitisation are avoided for all identified uses, to document in appropriate detail the operational conditions and risk management measures and revise the risk characterisation accordingly.

## 5. Exposure assessment and risk characterisation (Annex I, Section 5.1.1.) for human health; description of PPE (personal protective equipment)

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be described in the CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate RMMs can be prescribed by actors in the supply chain. Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet (SDS) in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn, protection equipment for parts of the body other than the hands and respiratory protection shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of exposure in accordance with Annex II, section 8.2.2.2.(b)(i), (ii) and 8.2.2.2.(c) respectively). The information provided in the Safety Data Sheet shall be consistent with information in the Chemical Safety Report (Annex II, section 0.1.2. of the REACH Regulation).

In the CSR, you have provided non-specific advice about personal protective equipment. For instance, you state that "*chemically resistant gloves conforming to EN374 and respirator with APF of 10*" should be used. You have also provided some information on PPE in the Section 11 (Guidance on safe use) in the technical dossier (IUCLID): "*Inhalation: mask (in case of insufficient ventilation); Eyes: Safety glasses; Skin: avoid contact by using chemical resistant gloves when necessary. Depending on the workplace use special clothing to limit pollution by staff smelly clothes. Follow normal hygiene rules.*"

ECHA notes that specific detailed information on the recommended personal protective equipment is missing both from the CSR and from the information on safe use (section 11) within the IUCLID dossier.

To ensure the safe use of a substance, Annex I, Section 5.1.1. requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans.

Gloves are reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. Generally, gloves that are capable of preventing exposure to the skin for a pre-determined duration shall be specified. Typically, this information, as a minimum, has to specify the glove material and, depending on the exposure scenarios, may also need to include the breakthrough time and thickness of the glove material. Gloves need to be manufactured and tested according to CEN standard EN 374:2003 – Gloves giving protection from chemicals and micro-organisms.

Respiratory protection is reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent inhalation exposure to the substance. Typically, this information, as a minimum, has to specify the type/class of filters that are capable of preventing inhalation exposure for a pre-determined duration and delivering the assessment protection factor specified by you.

Where protective clothing is specified as a means to reduce exposure to the registered substance it has to be capable of providing the required barrier properties. This can only be assured through provision of clothing that has been tested to ensure a minimum performance against splash/spray/jet challenge. The minimum standard for liquid chemicals is "Type 6" protective clothing that meets the standard of EN 13034:2005 – Chemical protective clothing offering limited protection against liquid chemicals (type 6 and type PB [6] equipment), typically disposable coveralls. Unspecified workwear that has not been tested according to the appropriate standards for permeation and penetration resistance is

not chemical protective clothing, as defined, and is unlikely to provide any demonstrable protection. It may even act as a longer-term source of exposure.

Therefore, pursuant to Article 41(1) and (3) you are requested to provide documentation for the recommended personal protective equipment, i.e. skin protection (hand and body protection) and respiratory protection:

- further specify the type of glove material and breakthrough times;
- further specify the filter type/class for the respiratory protective equipment;
- further specify the type and quality of protective clothing.

## 6. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for human health; consumer exposure assessment

You have provided many consumer uses for the registered substance: consumer uses of several products [PC 3 (air care products), 8 (biocidal products), 31 (polishes and waxes), 35 (washing and cleaning products)] and consumer exposures via service life of many articles [AC 8 (paper articles), 13 (plastic articles), 31 (scented cloths), 32 (scented eraser), 34 (scented toys), 35 (scented paper articles), 36 (scented CD) and 0 (other)]. You have predicted the consumer exposure by using ECETOC TRA Consumer version 3 tool.

ECHA notes some deficiencies with your consumer exposure and risk assessments:

1. You have performed exposure and risk assessment for the consumer use of products and the combined RCRs are above 1 or very close to 1 in all ESs. For example, in consumer contributing scenario CCS4 (PC 31, use 1 and 2) in ES7 (Consumer use), the combined RCRs are [redacted] and [redacted], respectively.
2. Your exposure and risk assessment shows high RCRs for article service life in ES8 and ES9 in the CSR. The combined RCRs are above 1 and the RCR for dermal exposure alone is close to 1, being [redacted] in all scenarios.
3. You have very similar CCSs for all article service life ESs (ES8 (Service life - consumers) and ES9 (Service life - consumers)) in CSR. All the parameters, except the article type, are exactly the same in CCSs e.g. product ingredient fraction by weight, exposure time and amount of the product used per application. As a consequence, also the exposure estimations and RCRs are the same in all ESs. ECHA notes that the type of material (matrix) e.g. paper, plastic, textile, wood material, ceramics and the type of articles have an effect on exposure release potential and most relevant exposure route. In particular the following drivers of exposure can be considered: large surfaces, direct and intense skin contact, products for use by children (mouthing route to be considered), articles meant to get in contact with food.
4. Your exposure assessment and risk characterisation for consumer uses is lacking applied risk management measures (e.g. product integrated risk management measures).

ECHA notes, that the exposure assessment for consumer uses should be carried out according to ECHA's *Guidance on information requirements and chemical safety assessment*, Chapter R.15: Consumer exposure assessment (version 3.0, July 2016) and ECHA's *Guidance on information requirements and chemical safety assessment*, Chapter E, Risk characterisation (version 3.0, May 2016), section E.3.4, pages 22 to 36. The risk management measures for consumer use are limited and product-integrated measures are often the only appropriate RMMs for consumer products. According ECHA Guidance (page

30): "*Risk management measures for corrosive or sensitising substances in consumer preparations are limited. Compliance in the implementation of technical controls and PPE is usually impossible to determine in a consumer population, therefore product-integrated measures (such as the maximum volume of the bottle, concentrations used, high viscosity of the product, child resistant fastening) are often the only appropriate RMMs that can be applied. Diluted preparations, child-resistant fastenings and product formulation, which prevent splashes (e.g. viscous or paste-like formulation) as well as labelling and correct use instructions are commonly recognized RMMs for consumer products*".

As previously stated, the registered substance is a skin sensitising substance. The outcome of the risk characterisation should be used to decide whether safe use can be demonstrated or not through comparison with DNELs or by the likelihood of effects being avoided. ECHA notes, that currently the safe use of consumer products and articles has not been demonstrated in your dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to revise consumer exposure assessment demonstrating the likelihood that skin sensitising effects are avoided for consumers (ES7, ES8 and ES9) and detail the operational conditions and risk management measures and revise the risk characterisation accordingly.

EXPOSURE ASSESSMENT AND RISK CHARACTERISATION FOR ENVIRONMENT

Pursuant to Article 41(1)(c) of the REACH Regulation, ECHA may examine any registration in order to verify that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate.

Annex I, Section 0.7. of the REACH Regulation, defines the concept of exposure scenarios as "*the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users*".

Annex I, Section 5.1.1 of the REACH Regulation specifies the sets of conditions that shall be documented in the exposure scenarios. This shall include a description of the Operational conditions (OCs) consist and of the Risk management measures (RMMs).

Operational conditions consist of a set of actions, tools, parameters such as amount of substance, duration and frequency of release, type of use (e.g. indoor or outdoor), containment of process (open or closed), continuous or batch process (leading to an intermittent release), capacity of surroundings (e.g. dilution factor), etc. having an impact on the release and the exposure. Risk management measures consist of technologies and procedures aimed at either reducing the releases and/or preventing a release pathway. Examples of risk management measures intended to reduce release are filters, scrubbers, biological or physico-chemical wastewater treatment plants, etc. Both OCs and RMMs have an impact on the type and amount of release and the resulting exposure.

Pursuant to Annex I, Section 5.2. of the REACH Regulation, the exposure shall be estimated for each exposure scenario developed and shall take account of the conditions of use of substance, as described in the respective exposure scenarios.

## 7. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment, release factors

Pursuant to Annex I, Section 5.2.1 of the REACH Regulation, the exposure shall be estimated for each exposure scenario developed. The exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and the operational conditions (OCs) described in the exposure scenarios (ES) have been implemented.

Where measurement of emissions are available, a description of the methodology applied for measurements and data collection should be provided in order to assess the adequacy and the representativeness of the measured data. In most cases, emission will not be measured but calculated from a release factor applied to the tonnage assumed for the use. The release factor expresses the fraction of the used amount being released to a given release route. ECHA guidance R.16 (Table R.16-7 of the Appendix A.16-1 of the *Guidance on information requirements and chemical safety assessment* Chapter R.16 (version 3.0, February 2016) specifically provides default release factors associated with different Environmental Release Categories (ERCs). These default release factors can be used for a first tier assessment of the emissions. However, better information may be available that could then be used instead. In particular, release factors can be refined by taking into account specific RMMs and OCs. It is therefore important to explicitly link such RMMs and OCs to the release factors and communicate them properly to the downstream users in the exposure scenarios.

In Section 9 of the CSR you have developed 9 exposure scenarios: 1) manufacturing; 2) formulation of fragrance compounds; 3) formulation of fragrance end-products; 4) use at industrial site (industrial end-use of washing and cleaning products); 5) professional end-use of washing and cleaning products; 6) professional use of polishes and wax blends; 7) consumer use; 8) service life (consumers); 9) service life (consumers).

ECHA notes that for exposure scenarios 1 to 4, the release factors you have used for your assessment are not based on the default values recommended in Appendix A.16-1 of the ECHA's *Guidance on information requirements and chemical safety assessment* Chapter R.16 (version 3.0, February 2016) and that you have not provided a justification for deviating from those recommended values. In particular, you have not described any specific OC or RMM that could justify the release factors applied for those exposure scenarios.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to use the default release factors recommended in ECHA Guidance R.16 *or* to provide a detailed justification (e.g. based on RMMs and OCs) for not using the default release factors as recommended in ECHA Guidance R.16 for the estimation of environmental exposure. You shall revise your exposure assessment and risk characterisation accordingly.

## 8. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment, description of the exposure scenarios

In Section 9 of the CSR you have developed 9 exposure scenarios: 1) manufacturing; 2) formulation of fragrance compounds; 3) formulation of fragrance end-products; 4) use at industrial site (industrial end-use of washing and cleaning products); 5) professional end-use of washing and cleaning products; 6) professional use of polishes and wax blends; 7) consumer use; 8) service life (consumers); 9) service life (consumers).

ECHA notes that ES 8 and 9 do not include information on the conditions of use for the environmental contributing scenarios: service life, consumers 1 and 2. This information shall be included in the CSR. ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.16 provides recommendations for the default values. ECHA considers that an adequate and detailed justification should be provided in the CSR in case that other than default values are used in the exposure estimation.

Besides, ECHA notes that there are inconsistencies along your CSR in the description of your exposure scenarios that you shall clarify:

- The quantity reported in Section 9.0. of your CSR for exposure scenarios 1, 2 and 3 is [redacted] tonnes/year, while within the exposure scenarios (e.g. Sections 9.1 or 9.2 of your CSR), a tonnage of [redacted] tonnes/year is used for the exposure scenario calculations.
- in Section 2 of your CSR, 7 exposure scenarios are presented, while Section 9 of your CSR describes 9 exposure scenarios.
- The Environmental Release Category (ERC) mentioned in Section 2 of your CSR are not always consistent with those presented in Section 9 of your CSR (e.g. ERC 5 is mentioned in Section 2 of your CSR, but not in Section 9; less Environmental release categories are described in Section 9.0.1. compared to Section 2 or compared within each exposure scenario section (e.g. Section 9.5, 9.6 or 9.7)).

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation you are requested to:

- report the conditions of uses applicable to exposure scenarios 8 and 9,
- ensure the consistency in the information provided on the exposure scenarios through the different sections of your CSR, and
- revise your exposure assessment and risk characterisation accordingly.

*Notes for your consideration*

The revised PNECs requested with this decision shall be taken into account when assessing the related risks.

## Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 30 August 2017.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-60 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

## Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.